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Buffalo, NY 14228
(800) 343-2324
(716) 835-7000
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www.buffalofilter.com
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JUN - 9 2000

K000904

510(k) Summary
PenAdapt 10

Manufacturer	Medtek Devices, Inc. (d/b/a Buffalo Filter) 595 Commerce Drive Buffalo, NY 14228
Manufacturing Location	Same
Contract Sterilizer	For Gamma/E-beam Radiation Sterilization: SteriGenics International 305 Enterprise Drive Westerville, OH 43081 For Ethylene Oxide Sterilization: Not yet determined
Telephone/FAX/Email	Tel (716)-835-7000 Fax: (716)-835-3414 Email: kathy.selover@buffalofilter.com
Contact Person	Kathleen H. Selover
Device Trade Name	PenAdapt 10
Common Name	Smoke Aspiration Tip
Classification Name	Accessory to surgical exhaust apparatus
ProCode	79FYD
Predicate Device	SE-100 Smoke Aspiration Tip manufactured by Implantech Associates. Originally submitted by Inamed under 510(k) K931548.

World Leader in Surgical Smoke Evacuation™

K000904

Description	An elastomer sheath with a built-in air passage designed to fit co-axially over an electrosurgical pencil or pencil-like device. The distal end is connected via surgical tubing and/or hoses to a vacuum source. Supplied both as a stand- alone device and configured with a variety of lengths of surgical tubing/hoses.
Intended Use	PENADAPT 10 is intended for removing smoke, particles and body fluids from the point of surgical activity during medical procedures that use an electrosurgical (ESU) pencil or pencil-like device for cutting and/or cauterizing.
Physical/Technical Comparison	Both the device and the predicate are made from a silicone elastomer, are of the same general size and shape and have the same intended use. Both devices require attachment to a vacuum or suction apparatus in order to aspirate smoke and fluid from the surgical site.
Performance Summary	PenApapt 10 is capable of maintaining adequate air flow to allow for adequate aspiration of smoke and body fluids found at the site of surgical activity.
Biocompatibility Testing	The material used for the manufacture of PenAdapt 10 has undergone biocompatibility testing and has been found to be non-irritating, non-cytotoxic and non-sensitizing.
Sterility and Shelf Life	The device is sterile processed using gamma (or e-beam) radiation or ethylene oxide. Method of sterilization is dependent upon the device's final configuration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2000

Ms. Kathleen H. Selover
Regulatory Affairs Manager
Buffalo Filter, Company, Incorporated
595 Commerce Drive
Buffalo, New York 14228

Re: K000904
Trade Name: PenAdapt 10
Regulatory Class: II
Product Code: FYD
Dated: May 11, 2000
Received: May 16, 2000

Dear Ms. Selover:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE FORM: Revised 5/3/00

510(k) Number, if known: K000904

Device Name: Medtek Devices, Inc. (d/b/a Buffalo Filter) PenAdapt 10

Indications for Use:

Indications for Use:

This device is an aspiration sheath that fits over an electrosurgical pencil body and leaves the tip or blade exposed. This device is an accessory to an electrosurgical unit (ESU).

The device is used to remove smoke, particles and body and other casual fluids from the point of surgical activity during surgical procedures that use ESU for cutting and cauterizing. This device is used in conjunction with a suction (vacuum) source.

Contraindications

This device should not be used for microsurgery.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000904

Prescription Use _____ OR Over-the-Counter-Use ✓ (Per 801.109)